510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name:	Toshiba America Medical Systems, Inc.
Address:	PO Box 2068,2441 Michelle Drive Tustin, CA 92781-2068
Contact:	Paul Biggins, Sr. Manager of Regulatory Affairs
Telephone No.:	(714) 730-5000
Facsimile No.:	(714) 730-1310

Device Proprietary Name:	SSA-770A, APLIO Version 4
Common Name:	Diagnostic Ultrasound System

Classification:

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Regulatory Class:	п
Review Category:	Tier II
Panel:	Radiology

Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [Fed.Reg.No.:892.1550] Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [Fed.Reg.No.:892.1560] Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

- 1) Toshiba SSA-770A, Aplio Diagnostic Ultrasound; 510(k) control number k013633
- Toshiba SSA-700A, AplioSL Diagnostic Ultrasound; 510(k) control number K022400
- Acuson Sequoia Signature II Diagnostic Ultrasound; 510(k) control number k022567
- 4) GE Vingmed Ultrasound System FiVe, 510(k) control number K991842.

Device Description:

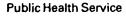
The APLIO Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz. This submission is to clear cardiac packages already in place on predicate devices.

Intended Use:

The APLIO is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular, musculo-skeletal (both conventional and superficial) and laparoscopic.

Safety Considerations:

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601 (applicable portions), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.





AUG - 6 2003

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Toshiba America Medical Systems, Inc. % Ms. Laura Danielson Responsible Third Party TÜV Product Service 1775 Old Highway 8 NEW BRIGHTON MN 55112-1891

Re: K032281

Trade Name: SSA-770A – Version 4, APLIO Diagnostic Ultrasound System Regulation Number: 21 CFR 892.1550 Regulation Name: Ultrasonic pulsed doppler imaging system Regulation Number: 21 CFR 892.1560 Regulation Name: Ultrasonic pulsed echo imaging system Regulation Number: 21 CFR 892.1570 Regulation Name: Diagnostic ultrasonic transducer Regulatory Class: II Product Code: 90 IYN, IYO, and ITX Dated: July 23, 2003 Received: July 24, 2003

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SSA-770A – Version 4, APLIO Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>PST-25AT</u> <u>PVT-375AT</u>

PVT-661VT PLT-805AT PST-20CT PLT-1204AX PC-20M PET-510MB **PLT-1202S** PET-704LA PST-37CT PST-30BT PLT-704AT PLT-1204AT **PVT-375AX** PST-65AT PLT-604AT PST-50AT PLT-308P

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon Director, Division of Reproductive, Abdominal and Radiological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure(s)

System X Transducer

Model SSA-770A 510(k) Number(s)

	Mode of Operation												
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q	
Ophthalmic											T		
Fetal	P	P	Р	P	P	P	Р	P	Р		1		
Abdominal	P	P	P		P	Р	P	Р	Р		1		
Intraoperative (Specify)**	P	P	P		Р	Р	P	P	Р		1		
Intraoperative													
Pediatric	P	P	P	P	P	Р	P	Р	P				
Small Organ (Specify)***	P	P	P		P	Р	Р	Р	Р		1	<u> </u>	
Neonatal Cephalic	P	P	P	P	P	Р	Р	P	Р				
Adult Cephalic	P	P	P	P	P	P	Р	Р	P				
Cardiac	P	P	P	P	Р	Р	Р	Р	Р	E	N	N	
Transesophageal	P	P	Р	P	P	Р	Р	Р	Р	E	1	N	
Transrectal	P	P	P		P	Р	Р	Р	Р				
Transvaginal	P	P	P		P	Р	Р	Р	Р		1		
Transurethral													
Intravascular													
Peripheral Vascular	P	P	P		Р	P	Р	Р	P		<u> </u>		
Laparoscopic	P	P	P		Р	P	Р	Р			1		
Musculo-skeletal Superficial	P	P	P		Р	P	Р	Р	P				
Musculo-skeletal Conventional	P	P	P		Р	Р	Р	P	Р				

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

$\mathbf{E}^{1} - \mathbf{A}$	Added via LTF against SSA-700A 510(k) control number K022400
Previ	ous 510(k) for this device k013633
**	Abdominal
***	For example: thyroid, parathyroid, breast, scrotum and penis

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(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number _

System Transducer X Model PST-25AT 510(k) Number(s)

		Mode of Operation											
Clinical Application	В	м	P W D	C W D	Color Doppier	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q	
Ophthalmic													
Fetal													
Abdominal													
Intraoperative (Specify)													
Intraoperative Neurological													
Pediatric	P	P	P	P	P	Р	P	Р	Р				
Small Organ (Specify)													
Neonatal Cephalic													
Adult Cephalic													
Cardiac	P	P	P	P	Р	Р	Р	Р	Р	E		N	
Transesophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral Vascular													
Laparoscopic													
Musculo-skeletal													
Superficial													
Musculo-skeletal													
Conventional							1						

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

E¹ – Added via LTF against SSA-700A 510(k) control number K022400 Previous 510(k) for this device k013633

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number ______ V03228

System Transducer X Model PVT-375AT 510(k) Number(s)

	Mode of Operation												
Clinical Application	В	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q	
Ophthalmic													
Fetal	P	P	P		P	P	P	P	Р	<u></u>			
Abdominal	P	P	P		P	P	P	P	P				
Intraoperative (Specify)						[L	
Intraoperative Neurological						L		ļ					
Pediatric	P	P	P		<u>P</u>	P	Р	P	P			<u> </u>	
Small Organ (Specify)								 				ļ	
Neonatal Cephalic	L						ļ	ļ				···	
Adult Cephalic						ļ	ļ	<u> </u>					
Cardiac								ļ					
Transesophageal								[
Transrectal					l							ļ	
Transvaginal													
Transurethral		- -					<u> </u>	<u> </u>				[
Intravascular								L			<u> </u>		
Peripheral Vascular								L			L	ļ	
Laparoscopic								L					
Musculo-skeletal Superficial								L	·	ļ	L	L	
Musculo-skeletal								{			ļ		
Conventional					}							<u> </u>	

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device k013633

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number _____ K03228 |

System _____ Transducer _X Model _____ PVT-661VT 510(k) Number(s)

	Mode of Operation											
Clinical Application	В	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic	Π											
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal	P	P	P		Р	P	Р	Р	Р			
Transvaginal	P	P	P		R	P	Р	Р	Р			
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal												
Superficial												
Musculo-skeletal												
Conventional												

N= new indication; $P \doteq$ Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

Previous 510(k) for this device k013633

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number ______ KDB228

	Mode of Operation											
Clinical Application	в	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q
Ophthalmic				\Box								
Fetal					[
Abdominal				\Box								
Intraoperative (Specify)					I							
Intraoperative Neurological												
Pediatric			\square	\Box								
Small Organ (Specify)***	P	P	P	\Box	Р	P	Р	P	Р			
Neonatal Cephalic			\square	\square								
Adult Cephalic				\square								
Cardiac			\Box	\Box								
Transesophageal			\Box	\Box								
Transrectal			\Box	\Box								
Transvaginal			\Box	\Box								
Transurethral			\Box	\Box	1							
Intravascular			\Box									
Peripheral Vascular	P	P	P	\Box	P	P	P	Р	Р			
Laparoscopic				\Box								
Musculo-skeletal Superficial	P	P	P		Р	Р	Р	Р	Р			
Musculo-skeletal Conventional	Р	P	P		Р	Р	Р	Р	Р			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

*** For example: thyroid, parathyroid, breast, scrotum and penis Previous 510(k) for this device k013633

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(Division Sign-Off) Division of Reproductive, Abdominel, and Radiological Devices 510(k) Number _____ KO3228 |

System ____ Transducer _X

Model <u>PST-20CT</u> 510(k) Number(s)

<u></u>							Mode o	f Operati	on			
Clinical Application	в	м	P W D	C ¥ D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q
Ophthalmic												
Fetal	P	P	P	P	Р	P	P	P	Р			
Abdominal					_							L
Intraoperative (Specify)											L	
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic	P	P	P	P	Р	Р	Р	P	P			
Adult Cephalic	P	P	P	P	P	P	P	P	Р			
Cardiac	P	P	P	P	P	Р	Р	P	Р			
Transesophageal												
Transrectal												
Transvaginal				Į								
Transurethral												
Intravascular												_
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal												
Superficial	1	<u> </u>	[l		ļ	<u> </u>	ļ			
Musculo-skeletal					1		ł					1
Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device k013633

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number ______ K03228 |

System _____ Transducer _X Model ____PLT-1204AX ______ 510(k) Number(s)

	Γ						Mode o	f Operati	on			
Clinical Application	в	м	P W D	C ₩ D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 ТНІ	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative												
Neurological												
Pediatric												
Small Organ (Specify)***	P	P	P		Р	Р	Р	P	P			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	Р		Р	Р	Р	P	P			
Laparoscopic												
Musculo-skeletal	P	P	P		, P	Р	Р	P	Р			
Superficial												
Musculo-skeletal	P	P	P		P	P	Р	Р	Р			
Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

Previous 510(k) for this device k013633

*** For example: thyroid, parathyroid, breast, scrotum and penis

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(Division Sign-Off) Division of Reproductive, Abdominel, and Radiological Devices 510(k) Number ______ K032281

System Transducer X Model PC-20M 510(k) Number(s)

	Mode of Operation												
Clinical Application	В	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q	
Ophthalmic			<u>'</u>			L	L	L			L		
Fetal								ļ	L		L		
Abdominal									L				
Intraoperative (Specify)		\Box	\Box				ļ	L			Į	 	
Intraoperative Neurological													
Pediatric				P	l		ļ	L	L	!	L	ļ	
Small Organ (Specify)										l	L		
Neonatal Cephalic									·		L	 	
Adult Cephalic										[
Cardiac				P				L	L	l	L	L	
Transesophageal	1							L		L	L	L	
Transrectal		Γ									L	L	
Transvaginal		Γ						L	L	L	L	ļ	
Transurethral		Γ						L		l	L	<u> </u>	
Intravascular				E						L	L	<u> </u>	
Peripheral Vascular											L	ļ	
Laparoscopic		Γ							L	ļ	ļ		
Musculo-skeletal Superficial			Γ	Γ									
Musculo-skeletal Conventional		T											

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device k013633

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Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number ______ K03228

System _____ Transducer _X Model _____ PET-510MB 510(k) Number(s)

							Mode o	f Operati	on			
Clinical Application	В	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal	P	P	P	P	Р	Р	P	P	Р	E		N
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal												
Superficial												
Musculo-skeletal												
Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

E¹- Added via LTF against SSA-700A 510(k) control number K022400 Previous 510(k) for this device k013633

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number_____K03228/

System _____ Transducer _X Model _________ 510(k) Number(s)

							Mode o	f Operatio	on			
Clinical Application	B	м	P ₩ D	C ¥ D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q
Ophthalmic												
Fetal											1	
Abdominal												
Intraoperative (Specify)	P	P	P		P	Р	Р	P	Р		1	
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)***	P	P	P		Р	Р	Р	Р	Р			
Neonatal Cephalic											1	
Adult Cephalic	Γ										1	
Cardiac											1	
Transesophageal												
Transrectal										14	1	
Transvaginal											1	
Transurethral											<u> </u>	
Intravascular												
Peripheral Vascular	P	P	Р		Р	Р	Р	Р	Р			
Laparoscopic												
Musculo-skeletal Superficial	P	P	Р		Р	Р	Р	Р	Р		1	
Musculo-skeletal Conventional	P	P	Р		Р	Р	Р	Р	Р			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

Previous 510(k) for this device k013633 *** For example: thyroid, parathyroid, breast, scrotum and penis

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number _____ K_03278/

System <u>Transducer X</u> Model <u>PET-704LA</u> 510(k) Number(s)

STO(K) Number(S)

·····	Γ						Mode of	f Operati	on			
Clinical Application	в	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI- Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)					_							
Neonatal Cephalic												
Adult Cephalic						l						
Cardiac												L
Transesophageal												
Transrectal						<u> </u>					ļ	
Transvaginal											<u> </u>	ļ
Transurethral						1						L
Intravascular											Į	
Peripheral Vascular								L			<u> </u>	ļ
Laparoscopic	P	P	P		P	P	Р	P	<u> </u>		<u> </u>	I
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

Previous 510(k) for this device k013633

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number______K032281

System _____ Transducer _X Model _____ PST-37CT______ 510(k) Number(s)

			_				Mode of	Operatio	on			
Clinical Application	в	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal	E	E	E	E	E	E	E	E	E			
Abdominal	E	E	E		E	E	E	E	E			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	E	E	E	E	E	E	E	E	E			
Small Organ (Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular						l						
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number ______ K 03228

System _____ Transducer _X Model _____ PST-30BT ______ 510(k) Number(s)

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							Mode of	Operatio	on			
Clinical Application	В	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative												
Neurological												
Pediatric	E	E	E	E	E	E	E	E	Ē			
Small Organ		ł							İ			
(Specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac	E	E	E	E	E	E	E	E	E	E	N	N
Transesophageal												
Transrectal												
Transvaginal		_				L	·				L	
Transurethral				_								
Intravascular	1											
Peripheral Vascular												
Laparoscopic .		L					· ·					<u> </u>
Musculo-skeletal												
Superficial				L								
Musculo-skeletal												
Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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m (Division Sign-Off) 0 Division of Reproductive, Abdominal, and Radiological Devices KD32 510(k) Number ____

System Transducer X Model PLT-704AT 510(k) Number(s)

							Mode of	Operatio	on			
Clinical Application	в	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic								. <u> </u>				
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												L
Small Organ (Specify)***	E	E	E		E	E	E	E	E		L	
Neonatal Cephalic												
Adult Cephalic												
Cardiac								<u> </u>				Í
Transesophageal	Τ							<u> </u>				
Transrectal												
Transvaginal								<u> </u>		L	[L
Transurethral							<u> </u>			L		
Intravascular								<u> </u>				
Peripheral Vascular	E	E	Ē		Ē	E	E	E	E		[
Laparoscopic												
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E			
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

*** For example: thyroid, parathyroid, breast, scrotum and penis

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number _____ K032281

System Transducer X Model PLT-1204AT 510(k) Number(s)

							Mode of	Operatio	on			
Clinical Application	в	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal												
Abdominal							L					
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric					- 		ļ				ļ	
Small Organ (Specify)***	E	E	E		E	E	E	E	E		ļ	
Neonatal Cephalic							ļ			L	 	
Adult Cephalic											ļ	
Cardiac							L				ļ	
Transesophageal							L				<u> </u>	
Transrectal												
Transvaginal										ļ	L	
Transurethral	T								ļ		<u> </u>	ļ
Intravascular								<u> </u>		L	<u> </u>	ļ
Peripheral Vascular	E	E	E		E	E	E	E	E	L	l	
Laparoscopic									ļ	L	<u> </u>	<u> </u>
Musculo-skeletal Superficial	E				E	E	E	E	E			
Musculo-skeletal . Conventional	E	E	E		E	E	E	E	E			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

*** For example: thyroid, parathyroid, breast, scrotum and penis

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number_____KO32281

System Transducer X Model <u>PVT-375AX</u> 510(k) Number(s)

[_									
	\vdash						Mode of	f Operati	on			
Clinical Application	В	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal	E	E	E		E	E	E	E	E			
Abdominal	E	E	E		E	E	E	E	E			
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	E	E	E		E	E	E	E	E			
Small Organ (Specify)												
Neonatal Cephalic				\square						·		
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal												
Superficial												
Musculo-skeletal												
Conventional								1				

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

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System Transducer X Model PST-65AT 510(k) Number(s)

	Mode of Operation													
			[]				littoue of	Operation			I			
Clinical Application	В	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q		
Ophthalmic														
Fetal														
Abdominal														
Intraoperative (Specify)														
Intraoperative Neurological														
Pediatric	E	E	E	E	E	E	E	E	E					
Small Organ (Specify)														
Neonatal Cephalic	E	E	E	E	E	E	E	E	E					
Adult Cephalic														
Cardiac .	E	E	E	E	E	E	E	E	E	E				
Transesophageal														
Transrectal														
Transvaginal														
Transurethral														
Intravascular														
Peripheral Vascular														
Laparoscopic														
Musculo-skeletal Superficial														
Musculo-skeletal														
Conventional														

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

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System _____ Transducer _X Model _______ 510(k) Number(s)

							Mode of	Operatio	on			
Clinical Application	В	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal								[
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)***	E	E	E		E	E	E	E	E			
Neonatal Cephalic												
Adult Cephalic								<u> </u>				
Cardiac									· · · · · · · · · · · · · · · · · · ·			
Transesophageal								<u> </u>				
Transrectal										L	<u> </u>	
Transvaginal											<u> </u>	
Transurethral								ļ	L	ļ		l
Intravascular								ļ				L
Peripheral Vascular	E	E	E		E	E	E	E	E	l	<u> </u>	ļ
Laparoscopic											L	L
Musculo-skeletal	E	E	E		Е	E	E	E	E			
Superficial		1	<u> </u>			· · · ·		<u> </u>	<u> </u>	<u> </u>	l	
Musculo-skeletal	E	E	E		E	E	E	E	E		1	
Conventional			1			L	<u> </u>	J	<u> </u>	1	l	L

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

*** For example: thyroid, parathyroid, breast, scrotum and penis

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System _____ Transducer _X Model _____ST-50AT_____ 510(k) Number(s)

						<u> </u>	Mode of	f Operati	on			
Clinical Application	в	м	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												
Fetal								<u></u>				
Abdominal								<u> </u>				
Intraoperative (Specify)								ļ				
Intraoperative Neurological												
Pediatric	E	E	E	E	E	E	E	E	E			
Small Organ (Specify)	Τ											
Neonatal Cephalic	E	E	E	E	E	Ē	E	E	E		l	
Adult Cephalic							[L	
Cardiac	E	E	E	E	E	E	E	E	E	E		N
Transesophageal				_							L	
Transrectal							<u> </u>					
Transvaginal								L				
Transurethral								L				
Intravascular							[
Peripheral Vascular												
Laparoscopic									L		ļ	
Musculo-skeletal			[
Superficial						L	L		ļ			
Musculo-skeletal							ļ	1			[1
Conventional											l	L

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

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System Transducer X Model PLT-308P 510(k) Number(s)

						Mode of	f Operatio	on			
Clinical Application	в	м	P W D	 Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic											
Fetal											
Abdominal	E	E	E	E	E	E	E	E			
Intraoperative (Specify)	E	E	E	E	E	E	E	E			
Intraoperative Neurological											
Pediatric	E	E	E	E	E	E	E	E			
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal .											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal		\square									
Superficial											
Musculo-skeletal											
Conventional											

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: <u>Combined Modes: B/M; B/PWD;</u> <u>BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;</u> <u>CHI/2D; FEI/2D; CHI/BDF; FEI/BDF</u>

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